

Amended Claims

1. A transgenic non-human mammal containing an exogenous DNA sequence stably integrated in its genome, wherein said exogenous DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding protein C and a signal peptide, wherein said whey acidic protein promoter is specifically active in mammary cells and said signal peptide is effective in directing the secretion of said protein C into the milk of said transgenic mammal, wherein the activated form of said secreted protein C has an enzymatic activity of at least 50% as plasma-derived protein C, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

2. The transgenic non-human mammal of claim 1, wherein said protein C is human protein C, and wherein said DNA sequence encoding protein C further comprises portions of the non-coding regions of the human protein C gene.

3. The transgenic non-human mammal of claim 1, wherein said DNA sequence encoding human protein C comprises the human protein C gene from 21 basepairs upstream of the protein C start codon to the *NheI* site in the 3' end of the protein C gene.

4. The transgenic non-human mammal of claim 1, wherein said exogenous DNA sequence comprises a DNA sequence consisting essentially of the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene.

6. A process for the production of protein C, comprising the steps of:

(A) providing a non-human transgenic mammal characterized by an exogenous DNA sequence stably integrated in its genome, wherein said exogenous DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding protein C and a signal peptide, said promoter being specifically active in mammary cells and said signal peptide being effective in directing the secretion of said protein C into the milk of said transgenic mammal, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows;

(B) producing milk from said transgenic mammal, wherein said milk contains said secreted protein C, and wherein the activated form of said secreted protein C has an enzymatic activity of at least 50% as plasma-derived protein C;

(C) collecting said milk; and

(D) isolating said protein C from said milk.

7. The process of claim 6, wherein said protein C is human protein C, and wherein said DNA sequence encoding protein C further comprises portions of the non-coding regions of the human protein C gene.

8. The process of claim 6, wherein said DNA sequence encoding human protein C comprises the human protein C gene from 21 basepairs upstream of the protein C start codon to the *NheI* site in the 3' end of the protein C gene.

9. The process of claim 6, wherein said exogenous DNA comprises a DNA sequence consisting essentially of the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the

protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene.

11. A process for producing non-human transgenic mammals, comprising the steps of (A) providing a mixture containing a double-stranded DNA; (B) subjecting said mixture to anion-exchange high performance liquid chromatography to obtain purified double-stranded DNA; and thereafter (C) microinjecting an aqueous buffer solution containing said purified double-stranded DNA into an animal embryo, wherein said double-stranded DNA is selected from the group consisting of a double-stranded DNA comprising the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter, a double-stranded DNA comprising a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene, and a double-stranded DNA comprising a DNA sequence consisting essentially of the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter ligated directly or by a linker to a fragment of the human protein C gene beginning 21 basepairs upstream of the protein C start codon and ending at the *NheI* site in the 3' end of the protein C gene, wherein the activated form of protein C encoded by said double-stranded DNA has an enzymatic activity of at least 50% as plasma-derived protein C, and wherein said transgenic mammal is selected from the group consisting of mice, rats, rabbits, pigs, sheep, goats and cows.

12. A process for the production of a polypeptide in the milk of a transgenic non-human mammal, comprising the steps of:

(A) providing a non-human transgenic mammal characterized by an exogenous DNA sequence stably integrated in its genome, wherein said exogenous DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene, operably linked to a DNA sequence encoding said polypeptide and a signal peptide, said promoter being specifically active in mammary cells and said signal peptide being effective in directing the

secretion of said polypeptide into the milk of said transgenic mammal;

- (B) producing milk from said transgenic mammal, wherein said milk contains said secreted polypeptide;
- (C) collecting said milk; and
- (D) isolating said polypeptide from said milk.

14. A transgenic non-human mammal containing an exogenous DNA sequence stably integrated in its genome, wherein said exogenous DNA sequence comprises the 5' 4.2 kb *Sau3A* - *Kpn1* promoter fragment of the mouse whey acidic protein promoter, operably linked to a DNA encoding a polypeptide whereby said protein is expressed specifically in mammary cells of said transgenic mammal and said protein comprises a signal peptide, said peptide being effective in directing the secretion of said protein into the milk of said mammal.

16. An isolated DNA molecule which regulates the expression of a heterologous gene, wherein said DNA molecule consists of the 5' 4.2 kb *Sau3A* - *Kpn1* promoter of the mouse whey acidic protein gene.